

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing: 21 December 2000 (21.12.00)	
International application No.: PCT/EP00/05237	Applicant's or agent's file reference: 26239WO-29VE
International filing date: 07 June 2000 (07.06.00)	Priority date: 11 June 1999 (11.06.99)
Applicant: ELSENHANS, Olivier et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International preliminary Examining Authority on:
30 June 2000 (30.06.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer:</p> <p>J. Zahra</p> <p>Telephone No.: (41-22) 338.83.38</p>
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ENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 26239W0-29VE	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 00/ 05237	International filing date (day/month/year) 07/06/2000	(Earliest) Priority Date (day/month/year) 11/06/1999
Applicant F. HOFFMANN-LA ROCHE AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

METHOD AND APPARATUS FOR EXAMINING FLUIDS OF BIOLOGICAL ORIGIN

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

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☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

An extinction spectrum is approximated in a first wavelength range by a combination of a merely theoretical curve and the spectrum of the pure first substance in a first wavelength range, and this evaluation is repeated in a second wavelength range by approximating the measured spectrum (62) by a combination of a hypothetical curve, the spectrum (64) of the first component with the already determined concentration, and the spectrum (65) of the pure second component. The hypothetical curves are preferably straight lines which are defined by slope and ordinate section. In the praxis of the quality test of blood, bilirubin and hemoglobin may be quantitatively determined, whilst the background together with the lipid component can be qualitatively examined by means of the differential spectrum.

INTERNATIONAL SEARCH REPORT

International Application No

EP 00/05237

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N21/27

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

PAJ, WPI Data, INSPEC, COMPENDEX, IBM-TDB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 915 338 A (JEACLE) 12 May 1999 (1999-05-12) page 2, line 3 - line 6 page 5, line 19 - line 24 page 7, line 46 - page 8, line 13 page 8, line 19 - line 21	1, 2, 5, 13-15, 17
A	figure 4	4, 16
A	WO 91 04470 A (ADA TECHNOLOGIES) 4 April 1991 (1991-04-04) page 21, line 1 - page 22, line 19 page 26, line 10 - line 25 page 28, line 24 - line 28 figures 11, 12	1, 2, 4, 5
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

12 October 2000

Date of mailing of the international search report

19/10/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Thomas, R.M.

INTERNATIONAL SEARCH REPORT

International Application No

EP 00/05237

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 562 800 A (SHIMADZU) 29 September 1993 (1993-09-29) column 1, paragraph 1 - paragraph 2 column 5, line 2 - line 9; figure 1 -----	1,2,4,5

INTERNATIO SEARCH REPORT

...ormation on patent family members

Intern Application No

PCT/EP 00/05237

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0915338	A	12-05-1999	IE	81138 B	05-04-2000
			US	6028663 A	22-02-2000
WO 9104470	A	04-04-1991	US	5070246 A	03-12-1991
			AU	6062390 A	18-04-1991
			US	5272345 A	21-12-1993
EP 0562800	A	29-09-1993	JP	5272993 A	22-10-1993
			US	5442574 A	15-08-1995

"coefficients" would anyway appear to be involved in standard fitting techniques, so that the subject matter of claim 1 does not seem to be inventive over D1.

Dependent claims:

The dependent claims, as far as they can be understood, seem to relate to mere design modifications, consequential features of the basic system of claim 1, or conventional features, and thus do not add anything inventive to this claim.

claim 2: the approximated spectrum in D1 is the sum of a component and a baseline.

claims 3-7: not clear - see Item VIII

claim 8: in D1 spectra are subtracted. see e.g. page 8, line 5. Spectral subtraction techniques are described in D2, starting page 21.

claims 10-12: presumably conventional measurement requirements

claim 13: known from D1: see e.g. page 8, lines 14-18

Re Item VII

Certain defects in the international application

At least D1 should have been acknowledged in the description.

Re Item VIII

Certain observations on the international application

(The claims contain brackets and underlinings which cause confusion. The claims have been read as if the underlinings and the matter in brackets were not present).

[1] The claims are generally not clear since many of the symbols used have not been defined in the claims. For example, in claim 1 at line 14, the significance of 1.1 and 1, n in the wavelength term, is not clear; at line 18, the term $a_{i,s1}$ is not clear and $S1$ and $d1$ have not been defined. The terms should have been defined as necessary, so that the claims are self contained in this respect.

[2] The nature of the spectral functions and their coefficients is not comprehensible, and the manner of varying concentration not specified (claim 1), so the way in which the fitting is performed is not clear. Also the last feature of claim 1 attempts to define by the result to be achieved, rather than a definite concrete feature.

content of the suspensions. The method involves acquiring spectra, then fitting an estimated interfering component presence spectrum, made up of two functions, to the measured spectrum.

D2 discloses a method for measuring at least one component in a gas stream using spectral analysis. Various processing techniques are described, including (page 21) use of a stored library of spectra of differing component concentrations, and matching thereof to a measured spectrum, and (page 22) calculating a baseline by performing linear regression calculations.

D3 relates to fitting a baseline to a measurement spectrum.

3. Novelty and inventive step:

Claim 1:

For the analysis of claim 1, the features are split up as follows:

introductory passage: lines 6-10

step a: lines 12-14

step b: lines 15-23

step c: lines 24-32

D1 seems to disclose the introductory passage of claim 1, since it relates to a method of determining chlorophyll (target analyte) in a sample, in which other pigments (interfering component) are present and appear superimposed on the spectrum (see page 6, lines 38-56).

step a: a first extinction spectrum is measured - see page 7, line 48; an approximated spectrum is developed for phycocyanin by combining a Gaussian function (function for a first pure component - see claim 1, lines 21-23) with a baseline (function for background extinction). The combined function is fitted to the measured curve.

step c: any fitting process will inevitably involve minimizing a deviation as referred to in lines 26-28: in D1 standard fitting techniques are employed - see page 6, line 53. Also, the spectral range of the measurements is such that the interfering component may be determined - see D1, page 8, lines 9-10.

D1 does not seem to state specifically that the fitting is performed by varying the concentration of the interfering component and coefficients. However, this feature is not clear in claim 1 (see Item VIII below). Moreover, such variation of a parameter and

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

3

Applicant's or agent's file reference 26239WO-29VE/cs	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP00/05237	International filing date (day/month/year) 07/06/2000	Priority date (day/month/year) 11/06/1999
International Patent Classification (IPC) or national classification and IPC G01N21/27		
Applicant F. HOFFMANN-LA ROCHE AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 30/06/2000	Date of completion of this report 19.09.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Loades, M Telephone No. +49 89 2399 2184 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05237

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-25 as originally filed

Claims, No.:

4 (part), 5-11 as originally filed

1-3, 4 (part), 12-17 as received on 30/04/2001 with letter of 27/04/2001

Drawings, sheets:

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP00/05237

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 14-17.

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 14-17 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05237

1. Statement

Novelty (N)	Yes: Claims 1-13
	No: Claims
Inventive step (IS)	Yes: Claims
	No: Claims 1-13
Industrial applicability (IA)	Yes: Claims 1-13
	No: Claims

2. Citations and explanations **see separate sheet**

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re It m III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Apparently claims 14-17 are intended to be restricted in some way to the method of claim 1, but the wording thereof is not appropriate to ensure this, so that these claims might be considered as only to include the features actually referred to therein, indeed might relate to different "inventions" from claim 1.

Claim 14: It is not clear what is intended by the "apparatus" as opposed to the "analyser". Apparently the claim could have stated "System arranged to carry out the method of claim 1 comprising.... then the various items should have been listed. The processor programmed to carry out the series of calculation steps recited in claim 1 would be a feature of this system.

Claim 15: this deals with details of the construction of the sample cell. This should have been a dependent claim to the system claim 14, adding in the detail features required.

Claim 16: dependent on claim 15

Claim 17: would become redundant once claim 14 is properly drafted. (Again there is confusion as to what is the "apparatus" in relation to the "analyser").

(It is noted in passing, that the features of claims 14,15 and 17 all seem to be known from D1, while the dip-in type probe effectively claimed in claim 16 is conventional).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents are referred to in this report:

D1: EP-A-0 915 338 (JEACLE) 12 May 1999 (1999-05-12)

D2: WO 91 04470 A (ADA TECHNOLOGIES) 4 April 1991 (1991-04-04)

D3: EP-A-0 562 800 (SHIMADZU) 29 September 1993 (1993-09-29)

2. **Review of the prior art documents:**

D1 relates a to a photometric analysis method for water suspensions comprising measuring spectrum heights of the absorbance of a sample to obtain an estimate of the

content of the suspensions. The method involves acquiring spectra, then fitting an estimated interfering component presence spectrum, made up of two functions, to the measured spectrum.

D2 discloses a method for measuring at least one component in a gas stream using spectral analysis. Various processing techniques are described, including (page 21) use of a stored library of spectra of differing component concentrations, and matching thereof to a measured spectrum, and (page 22) calculating a baseline by performing linear regression calculations.

D3 relates to fitting a baseline to a measurement spectrum.

3. Novelty and inventive step:

Claim 1:

For the analysis of claim 1, the features are split up as follows:

introductory passage: lines 6-10

step a: lines 12-14

step b: lines 15-23

step c: lines 24-32

D1 seems to disclose the introductory passage of claim 1, since it relates to a method of determining chlorophyll (target analyte) in a sample, in which other pigments (interfering component) are present and appear superimposed on the spectrum (see page 6, lines 38-56).

step a: a first extinction spectrum is measured - see page 7, line 48; an approximated spectrum is developed for phycocyanin by combining a Gaussian function (function for a first pure component - see claim 1, lines 21-23) with a baseline (function for background extinction). The combined function is fitted to the measured curve.

step c: any fitting process will inevitably involve minimizing a deviation as referred to in lines 26-28: in D1 standard fitting techniques are employed - see page 6, line 53. Also, the spectral range of the measurements is such that the interfering component may be determined - see D1, page 8, lines 9-10.

D1 does not seem to state specifically that the fitting is performed by varying the concentration of the interfering component and coefficients. However, this feature is not clear in claim 1 (see Item VIII below). Moreover, such variation of a parameter and

"coefficients" would anyway appear to be involved in standard fitting techniques, so that the subject matter of claim 1 does not seem to be inventive over D1.

Dependent claims:

The dependent claims, as far as they can be understood, seem to relate to mere design modifications, consequential features of the basic system of claim 1, or conventional features, and thus do not add anything inventive to this claim.

claim 2: the approximated spectrum in D1 is the sum of a component and a baseline.

claims 3-7: not clear - see Item VIII

claim 8: in D1 spectra are subtracted. see e.g. page 8, line 5. Spectral subtraction techniques are described in D2, starting page 21.

claims 10-12: presumably conventional measurement requirements

claim 13: known from D1: see e.g. page 8, lines 14-18

Re Item VII

Certain defects in the international application

At least D1 should have been acknowledged in the description.

Re Item VIII

Certain observations on the international application

(The claims contain brackets and underlinings which cause confusion. The claims have been read as if the underlinings and the matter in brackets were not present).

1. The claims are generally not clear since many of the symbols used have not been defined in the claims. For example, in claim 1 at line 14, the significance of 1.1 and $1, n$ in the wavelength term, is not clear; at line 18, the term $a_{i,S1}$ is not clear and $S1$ and $d1$ have not been defined. The terms should have been defined as necessary, so that the claims are self contained in this respect.
2. The nature of the spectral functions and their coefficients is not comprehensible, and the manner of varying concentration not specified (claim 1), so the way in which the fitting is performed is not clear. Also the last feature of claim 1 attempts to define by the result to be achieved, rather than a definite concrete feature.